

UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH DAKOTA  
SOUTHERN DIVISION

<p>UNITED STATES OF AMERICA, <i>ex rel.</i> C. Dustin Bechtold, M.D. and Bryan Wellman, M.D.,</p> <p>Plaintiff/Relators,</p> <p>v.</p> <p>WILSON ASFORA, M.D., SANFORD HEALTH, SANFORD CLINIC, and MEDICAL DESIGNS, LLC,</p> <p>Defendants.</p>	<p>CIV. 16-4115-LLP</p> <p><b>THE UNITED STATES' NOTICE OF SETTLEMENT</b></p>
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Plaintiff United States of America, Relators C. Dustin Bechtold, M.D. and Bryan Wellman, M.D., and Defendants Sanford Health and Sanford Clinic have reached a settlement in this matter. Pursuant to the settlement agreement attached as Exhibit A, Sanford Health, Sanford Clinic, and Sanford Medical Center shall pay the settlement amount to the United States within thirty days. Upon receipt of the settlement amount, the United States and Relators will file a notice of dismissal of their claims in this action against Sanford Health and Sanford Clinic, pursuant to the terms of the settlement agreement.

Date: October 28, 2019.

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Assistant Attorney General  
Civil Division

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United States Attorney

/s/ Meghan K. Roche

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*Attorneys for the United States of America*

## SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the Defense Health Agency (DHA), acting on behalf of the TRICARE Program, and the United States Department of Veterans' Affairs (VA) (collectively, the United States); Sanford Health, Sanford Clinic, and Sanford Medical Center (collectively, Sanford); and Carl Dustin Bechtold, M.D., and Bryan Wellman, M.D. (collectively, Relators), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

## RECITALS

A. Sanford Health, and its subsidiaries Sanford Clinic and Sanford Medical Center, are South Dakota nonprofit corporations located in Sioux Falls, South Dakota. During the period of January 1, 2010 through June 30, 2019, Sanford Clinic employed Wilson Asfora, M.D. (Asfora), who provided healthcare services, including spinal surgeries, to patients at Sanford Medical Center, including beneficiaries covered by the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395–1395lll (Medicare), the Medicaid Program, 42 U.S.C. §§ 1396–1396w-5 (Medicaid), the TRICARE Program, 10 U.S.C. §§ 1071–1110b (TRICARE), and the Department of Veterans' Affairs, Veterans Health Administration, 38 U.S.C. Pt. II, Ch. 17 (VA).

B. On August 12, 2016, Relators filed a *qui tam* action in the United States District Court for the District of South Dakota captioned *United States ex rel. Bechtold, et al. v. Asfora, et al.*, No. 4:16-cv-04115-LLP (D.S.D.), pursuant to the *qui tam* provisions of the False Claims Act (FCA), 31 U.S.C. § 3730(b) (the Civil Action).

C. The United States contends that it has certain civil claims against Sanford arising from the conduct set forth in this Paragraph, which is referred to below as the "Covered Conduct":

1. During the time periods and for the products listed in this subparagraph, Asfora solicited and received from Medical Designs, LLC (MDLLC) and Aegis Spine, Inc. (Aegis) improper remuneration, including profit distributions, in exchange for Asfora's use of certain MDLLC and Aegis products, in violation of the Federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b). Sanford knew of the aforementioned kickback schemes and the legal risks associated with submitting claims to federal healthcare programs for surgeries in which Asfora improperly profited from his use of implantable devices distributed by his physician-owned distributorship (POD). Sanford, whether directly, indirectly, or vicariously, knowingly submitted and caused to be submitted to Medicare, Medicaid, TRICARE, and the VA the following claims resulting from violations of the AKS: Claims for Asfora's surgeries and professional services at Sanford Medical Center in which Asfora implanted in patients MDLLC Bullet Cages from July 1, 2012 to June 30, 2019; MDLLC cervical plates from April 1, 2016 to June 30, 2019; MDLLC Samba screws from April 1, 2013 to September 30, 2013; and Aegis devices from March 1, 2014 to September 30, 2015 (collectively, "Subject Claims").

2. Sanford was warned that many of Asfora's surgical procedures in which he used MDLLC or Aegis products were medically unnecessary in whole or in part. Two Sanford neurosurgeons warned Sanford's Chief Compliance Officer that, in their view, Asfora had ramped up the number of cages he used on patients based on financial considerations; Asfora had entered into a possible POD arrangement in order to profit from his use of pedicle screws; and Sanford was not taking a deep enough look at patient complaints and post-operative complications for Asfora's patients. Nevertheless, Sanford knowingly submitted and caused to be submitted Subject Claims for medically unnecessary procedures to Medicare, Medicaid, TRICARE, and the VA.

3. On August 19, 2019, Sanford informed Asfora in writing that his employment with Sanford would be terminated as of September 24, 2019. Effective September

24, 2019, Sanford terminated Asfora's employment. Furthermore, Sanford has taken steps to prohibit all Sanford physicians from profiting from their choice of medical devices to use in procedures at Sanford Medical Center.

D. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees, and costs.

E. This Settlement Agreement is neither an admission of liability by Sanford nor a concession by the United States that its claims are not well founded. Sanford denies the United States' allegations in Paragraph C.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

#### TERMS AND CONDITIONS

1. Sanford shall pay to the United States the sum of \$20,250,000, of which \$10,250,000 is restitution, plus interest at the rate of 2.125% per annum from August 21, 2019, and continuing until and including the date of payment (collectively, the Settlement Amount), no later than thirty (30) days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States receiving the Settlement Amount from Sanford and as soon as feasible after receipt, the United States shall pay the sum of Three Million Four Hundred Thousand Dollars (\$3,400,000.00) to Relators by electronic funds transfer.

3. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Sanford's full payment of the Settlement Amount, the United States releases Sanford Health, Sanford Clinic, and Sanford Medical Center from any civil or administrative

monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; or the common law theories of payment by mistake and unjust enrichment. This Agreement does not release any claims of any State.

4. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Sanford’s full payment of the Settlement Amount, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release Sanford Health, Sanford Clinic, and Sanford Medical Center together with their current and former parent corporations, subsidiaries and affiliates, and the corporate successors of any of them, from any civil monetary claim the Relators have on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-3733, that Relators, for themselves, their heirs, successors, attorneys, agents, and/or assigns otherwise would have standing to bring, including, without limitation, any claim that Relators asserted or could have asserted in the Civil Action. Notwithstanding the foregoing, this Release specifically excludes any and all claims pursuant to 31 U.S.C. § 3730(h), and Relators specifically reserve their right to recover reasonable expenses, attorneys’ fees, and costs under 31 U.S.C. § 3730(d).

5. In consideration of the obligations of Sanford in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Sanford, and conditioned upon Sanford’s full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal healthcare programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Sanford under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 6 (concerning excluded claims),

below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Sanford from Medicare, Medicaid, and other Federal healthcare programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding any term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal healthcare programs, and the suspension and debarment rights of any Federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable

under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relators' receipt of the payment described in Paragraph 2, Relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. Sanford waives and shall not assert any defenses Sanford may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. Sanford fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Sanford has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct, the Civil Action, and the United States' investigation and prosecution thereof.

10. Sanford fully and finally releases the Relators from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Sanford has asserted, could have asserted, or may assert in the future against the Relators, related to the Covered Conduct, the Civil Action, and the Relators' investigation and prosecution thereof.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE carrier or payer, VA carrier or



payer, or any state payer, related to the Covered Conduct; and Sanford agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, VA carrier or payer, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

12. Sanford agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395–1395lll and 1396–1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Sanford, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States’ audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Sanford’s investigation, defense, and corrective actions undertaken in response to the United States’ audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys’ fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment Sanford makes to the United States pursuant to this Agreement and any payments that Sanford may make to Relators, including costs and attorneys’ fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
  - (i) retain an independent review organization to perform annual reviews as

described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 12.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Sanford.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in nonreimbursable cost centers by Sanford, and Sanford shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Sanford or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Sanford further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Sanford or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Sanford agrees that the United States, at a minimum, shall be entitled to recoup from Sanford any overpayment plus applicable interest and penalties as a result of the

inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Sanford or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Sanford or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Sanford's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

13. Sanford agrees to cooperate fully, actively, and truthfully with the United States in any investigation and litigation in connection with or arising out of the Civil Action and any proceedings related to such Civil Action. Such cooperation shall include, but not be limited to, the following:

a. Upon request by the United States with reasonable notice, producing to the United States and not at the expense of the United States, complete and unredacted copies of all requested non-privileged documents, records, and other evidence in Sanford's possession, custody, or control relating to Asfora, MDLLC, or Sicage, LLC (Sicage), including, but not limited to, reports, memoranda of interviews, and records concerning any investigation that Sanford has undertaken, or that has been performed by another on Sanford's behalf, of any actions or arrangements by or involving Asfora, MDLLC, or Sicage that may implicate or involve the AKS and/or FCA;

b. Upon request by the United States with reasonable notice, making current Sanford directors, officers, and employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, at a mutually agreed-upon location;

c. Upon request by the United States with reasonable notice, using best efforts to (i) assist in locating former Sanford directors, officers, and employees identified by attorneys and/or investigative agents of the United States, and (ii) to make any such former Sanford directors, officers, and employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, at a mutually agreed-upon location; and

d. Upon request by the United States with reasonable notice, making current Sanford directors, officers, and employees available, and using best efforts to make former Sanford directors, officers, and employees available, to testify, consistent with the rights and privileges of such individuals, fully, truthfully, and under oath, without falsely implicating any person or withholding any information, at depositions, at trial, and at any other legal proceedings.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 15 (waiver for beneficiaries paragraph), below.

15. Sanford agrees that it waives and shall not seek payment for any of the healthcare billings covered by this Agreement from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims defined as Covered Conduct.

16. Upon the United States' receipt of the Settlement Amount, the United States and the Relators shall promptly file in the Civil Action a Notice of Dismissal pursuant to Rule 41(a)(1)

as to the United States' and the Relators' claims in the Civil Action against Sanford Health and Sanford Clinic. The Notice of Dismissal shall be with prejudice as to the United States' and the Relators' claims in the Civil Action against Sanford Health and Sanford Clinic as to the Covered Conduct and consistent with the terms and conditions of this Agreement. The Notice of Dismissal shall be without prejudice to the United States and with prejudice to the Relators as to all other claims against Sanford Health and Sanford Clinic in the Civil Action.

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of South Dakota. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement among the Parties. This Agreement may not be amended except by written consent of the Parties.

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on Sanford's successors, transferees, heirs, and assigns.

24. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

25. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

26. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 10/25/19

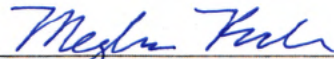
BY:



CHRISTOPHER TERRANOVA  
HARIN C. SONG  
Trial Attorneys  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: 10/25/19

BY:



MEGHAN K. ROCHE  
ELLIOT J. BAILEY  
Assistant United States Attorneys  
United States Attorney's Office  
District of South Dakota

DATED: 10/25/2019

BY:



LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

DATED: \_\_\_\_\_

BY:

BRYAN T. WHEELER  
Acting General Counsel  
Defense Health Agency  
United States Department of Defense

25. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

26. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHRISTOPHER TERRANOVA  
HARIN C. SONG  
Trial Attorneys  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

MEGHAN K. ROCHE  
ELLIE J. BAILEY  
Assistant United States Attorneys  
United States Attorney's Office  
District of South Dakota

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

DATED: 10/28/2019

BY: \_\_\_\_\_

BLEY.PAUL.NICHOL  
AS.1099873821

Digitally signed by  
BLEY.PAUL.NICHOLAS.1099873821  
Date: 2019.10.28 08:39:18 -04'00'

BRYAN T. WHEELER  
for Acting General Counsel  
Defense Health Agency  
United States Department of Defense

**SANFORD HEALTH**

DATED: 10/25/19

BY: Joann Kunkel  
JOANN KUNKEL  
Chief Financial Officer

DATED: 10/25/19

BY: Daniel M. Mulholland III  
DANIEL M. MULHOLLAND III  
Horty, Springer & Mattern, P.C.  
Counsel for Sanford Health

**SANFORD CLINIC**

DATED: 10/25/19

BY: Joann Kunkel  
JOANN KUNKEL  
Chief Financial Officer

DATED: 10/25/19

BY: Daniel M. Mulholland III  
DANIEL M. MULHOLLAND III  
Horty, Springer & Mattern, P.C.  
Counsel for Sanford Clinic

**SANFORD MEDICAL CENTER**

DATED: 10/25/19

BY: Joann Kunkel  
JOANN KUNKEL  
Chief Financial Officer


DATED: 10/25/19

BY: Daniel M. Mulholland III  
DANIEL M. MULHOLLAND III  
Horty, Springer & Mattern, P.C.  
Counsel for Sanford Medical Center



**RELATORS**

DATED: October 25, 2019

BY:   
CARL DUSTIN BECHTOLD, M.D.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
BRYAN WELLMAN, M.D.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
JAY P. HOLLAND  
VERONICA B. NANNIS  
Joseph Greenwald & Laake, PA  
Counsel for Relators

RELATORS

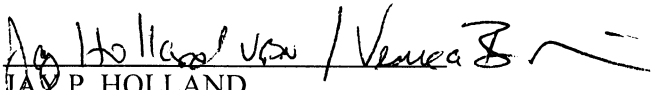
DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
CARL DUSTIN BECHTOLD, M.D.

DATED: 10/25/19

BY:  \_\_\_\_\_  
BRYAN WELLMAN, M.D.

DATED: 10/25/19

BY:  \_\_\_\_\_  
JAY P. HOLLAND  
VERONICA B. NANNIS  
Joseph Greenwald & Laake, PA  
Counsel for Relators